P19850.p13

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1623
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Attorney Docket No. P19850

In re application of : Dipak K. BANERJEE et al.

Serial No. : 09/779,447 Group Art Unit : 1623

Filed : February 9, 2001 Examiner : OWENS

For : METHODS FOR INHIBITING ANGIOGENESIS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an Election woth Traverse in the above-captioned application.

X Small Entity Status of this application under 37 C.F.R. 1.9 and 1.27 has been established ~~by a verified statement previously filed.~~

___ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.

___ An Information Disclosure Statement, PTO Form 1449, and references cited.

___ No additional fee is required.

The fee has been calculated as shown below:

Claims After Amendment	No. Claims Previously Paid For	Present Extra	Small Entity		Other Than A Small Entity	
			Rate	Fee	Rate	Fee
Total Claims: 92	*92	0	x 9=	$ 0.00	x 18=	$
Indep. Claims: 18	**18	0	x 42=	$ 0.00	x 84=	$
Multiple Dependent Claims Presented			+140=	$ 0.00	+280=	$
Extension Fees for Month				$55.00		$
			Total:	$55.00	Total:	$

*If less than 20, write 20
**If less than 3, write 3

___ Please charge my Deposit Account No. 19-0089 in the amount of $_____.

X A Check in the amount of $55.00 to cover the extension fee is included.

X The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-0089.

X Any additional filing fees required under 37 C.F.R. 1.16.

X Any patent application processing fees under 37 C.F.R. 1.17, including any required extension of time fees in any concurrent or future reply requiring a petition for extension of time for its timely submission (37 CFR 1.136)(a)(3).

Arnold Turk
Reg. No. 33,094

#11
1-9-03

P19850.A15 Application No. 09/779,447

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : BANERJEE et al.

Appl. No. : 09/779,447

Filed : February 9, 2001

For : METHODS FOR INHIBITING ANGIOGENESIS

Group Art Unit: 1623

Examiner: Owens

ELECTION WITH TRAVERSE

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This is in response to the requirement for restriction under 35 U.S.C. 121 mailed from the U.S. Patent and Trademark Office on November 5, 2002, which sets a one month period for response until December 5, 2002.

Applicants hereby request an extension of time for one month to extend the period for response until January 6, 2002 (January 5, 2003 being a Sunday), and are concurrently filing a formal Request for Extension of Time for one month accompanied by the government fee. If for any reason the formal Request for Extension of Time is not associated with the file and/or the government fee is deficient, this is an express request for any required extension of time to maintain the pendency of the application, and authorization for the Commissioner to charge any required fee for maintaining the pendency of the application including any required extension of time fee to Deposit Account No. 19-0089.

Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks which follow:

RESTRICTION REQUIREMENT

The Examiner has required restriction to one of the following inventions under 35 U.S.C. 121:

I. Claims 1, 4, 6, 8, 10-15 and 17, drawn to a method of inhibiting angiogenesis using a nucleoside, classified in class 514, subclass 42+.

II. Claims 5, 7, 9 and 18 drawn to a method of inhibiting angiogenesis using a nucleoside and at least one tunicamycin, classified in class 514, subclass 49+.

III. Claims 2, 3 and 16 drawn to a method of inhibiting angiogenesis using a nucleoside and glucosamine, classified in class 514, subclass 61.

IV. Claims 19-27 drawn to a method of inhibiting angiogenesis using an N– glycosylation inhibitor, classified in class 424, subclass 137.1+.

V. Claims 28-31, drawn to a method of inhibiting angiogenesis using an agent which induces ER stress in capillary endothelial cells, classified in class 514, subclass 8+.

VI. Claims 32-37 drawn to a method of inhibiting angiogenesis using an agent which induces unfolded protein response, classified in class 514, subclass 21+.

VII. Claims 38-42 and 73-77 drawn to a method of inhibiting angiogenesis using an agent which inhibits dolichol pathway, classified in class 514, subclass 23+.

VIII. Claims 43-47 and 78-82 drawn to a method of inhibiting angiogenesis using a biosynthesis inhibitor, classified in class 514, subclass 2+.

IX. Claims 48-53 drawn to a method of inhibiting angiogenesis using a transferase inhibitor, classified in class 424, subclass 94.1+.

X. Claims 54-58, drawn to a method of inhibiting angiogenesis using an agent which reduces Dol-P-Man synthase activity, classified in class 514, subclass 7+.

XI. Claims 59-66 drawn to a method of inhibiting angiogenesis using a non-peptide, classified in class 514, subclass 2+.

XII. Claims 67-72 drawn to a method of inhibiting angiogenesis comprising inducing accumulation of Factor VIII:C, classified in class 424, subclass 198.1+.

XIII. Claims 83-87, drawn to a method of inhibiting angiogenesis comprising administering a cell permeable apoptosis agent, classified in class 514, subclass 23+.

XIV. Claims 88-92 drawn to a method of inhibiting angiogenesis comprising administering a cell permeable agent to reduce intratumoral microvascular density, classified in class 514, subclass 2+.

ELECTION

In order to be responsive to the requirement for restriction, Applicants elect the invention set forth in Group I, claims 1, 4, 6, 8, 10-15 and 17, with traverse.

TRAVERSE

Notwithstanding the election of the claims of Group I in order to be responsive to the Restriction Requirement, Applicants respectfully traverse the Examiner's requirement for restriction.

Initially, Applicants respectfully submit that the requirement with respect to requiring restriction between at least Groups 1, II and III is improper, and should be withdrawn. In particular,

the Examiner's attention is directed to Applicants' specification, such as at page 37, beginning at page 9, wherein examples of nucleosides according to the present invention are disclosed, including nucleosides comprising glucosamine containing pyrimidine nucleoside, preferably a N-acetylated glucosamine containing pyrimidine nucleoside, with preferred examples of the glucosamine containing pyrimidine nucleoside being disclosed as including homologues of tunicamycin. Thus, the paragraph appearing in Applicants' specification at page 37, lines 9-19, discloses:

> The nucleoside is preferably a uridine, a cytidine, or a deoxythymidine, and more preferably a uridine. The nucleoside is preferably a glucosamine containing pyrimidine nucleoside, and more preferably a N-acetylated glucosamine containing pyrimidine nucleoside. Preferred examples of the glucosamine containing pyrimidine nucleoside include homologues of tunicamycin. Tunicamycin, a 840 dalton glucosamine-containing pyrimidine nucleoside, exists in 16 different homologues, differing mostly in the fatty acid side chain, which can be synthesized by *Streptomyces lysosuperificus*, as disclosed in ELBEIN, "Inhibitors of the Biosynthesis and Processing of N-linked Oligosaccharide Chain", Annu. Rev. Biochem., 56:497-534 (1987); and DUKSIN et al., "Relationship of the Structure and Biological Activity of the Natural Homologues of Tunicamycin", J. Biol. Chem., 257:3105-3109 (1982), the disclosures of which are herein incorporated by reference in their entireties.

Therefore, the claims in Groups I, II and III in recitation of nucleosides, including nucleosides having glucosamine, and wherein the nucleoside is at least one tunicamycin and functional derivatives thereof. Certainly, restriction between a recited genus and each sub-genus is improper. Accordingly, at a minimum, the restriction should be withdrawn with respect to at least Groups I, II and III containing claims 1-18.

Further, the requirement is deficient, because a complete supporting explanation and different fields of search are provided for requiring restriction only with respect to Groups I and X-XIV. Accordingly, the requirement is not adequately supported, and an action on the merits on each of the

pending claims is required in the absence of adequate support for restriction between each Group of invention. Accordingly, if the requirement is maintained, it is respectfully requested that complete support for the requirement be stated for each Group of invention.

Still further, the stated basis for requiring restriction between Groups I and X-XIV is not appropriate, because it asserts that, "Inventions I and X-XIV are related as product and process of use." Certainly, this is not the situation, because Groups I and X-XIV include claims directed to methods of inhibiting angiogenesis.

Still further, it is noted that the requirement for restriction omits one of the two criteria of a proper requirement as now established by U.S. Patent and Trademark Office policy, as set forth in MPEP 803, viz. that "an appropriate explanation" must be advanced by the Examiner as to the existence of a "serious burden" if a restriction were not required. Due to the aforementioned omission, it is respectfully submitted that the requirement for restriction is improper and, consequently, its withdrawal is respectfully requested.

Related to this, the requirement is traversed since there would not appear to be a serious burden to examine Applicants' application in total, and for which the appropriate claim fees have been paid. Applicants submit that it would be no serious burden on the Examiner to examine all of the pending claims, because a search for all of the claims in the above-identified application, should be made in order to do a complete and thorough search in view of the recognized relationship between the claims in the various Groups of invention, especially when each Group of invention includes claims directed to methods of inhibiting angiogenesis. Thus, at least for examination purposes, there should not be an undue burden to examine each of the Groups of invention.